K094043

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PREMARKET NOTIFICATION
510(k) SUMMARY
(As Required By 21 CFR 807.93)

AUG 17 2010

Date of Preparation: July 26, 2010

Applicant: AREX USA LLC
1335 Merrybrook Rd
Collegeville, PA 19403

Contact Individual: Ellen Hokanson, President
610-584-6870

Trade Name: AREX Ligamentotaxor (LTX)

Common Name: PIP Joint External Distraction Device

Regulation Number: 888.3040

Product Code: HTY

Classification Name: Pin, Fixation, Smooth

Classification: Class II

Predicate Device Name: BioSymetRic external fixator (K980370) marketed by Biomet Inc and the Compass System (K970713) of Smith and Nephew

Device Description: The Ligamentotaxor is an external fixation system intended for use in the treatment of complex fracture dislocations, stable and unstable dislocations, fracture luxations, and pilon fractures in the PIP joint.

The External Fixation System is as follows:

Description	Reference
Ligamentotaxor	LTX

Intended Use: The Ligamentotaxor is an external fixation system intended for use in the treatment of complex fracture dislocations, stable and unstable dislocations, fracture luxations, and pilon fractures in the PIP joint.

Technology: The fundamental scientific technology of the Arex Ligamentotaxor is substantially equivalent to the identified predicate device.

Substantial Equivalence:

The materials, design, and indications for use of the AREX Ligamentotaxor are similar to the identified predicate devices. In addition, distraction force testing of the Ligamentotaxor was performed; and, clinical data was provided to demonstrate outcomes similar to those of the identified predicate devices. No new technology or materials have been employed in the design.

To summarize the clinical data, the Ligamentotaxor was evaluated in a 10 site multicenter study in 4 countries. The device was used to treat 83 cases with various fractures and dislocations of the PIP. In 60 cases the Ligamentotaxor alone was used, other patients received additional tendon repair and/or osteosynthesis with additional pins or screws. There were 16 females and 67 males treated whose ages ranged from 17 to 89 years. The Ligamentotaxor was left in place for an average of 36 days. The mean follow-up for the patients was 15.2 months, ranging from 6 months to 38 months. For each patient, age, gender, mechanism of injury, dominant/non-dominant hand, Pelissier fracture class, duration of treatment, any further treatment, mode of rehabilitation, adverse events, flexion/extension range of motion, finger/thumb mobility, pain using the VAS 10 point scale, the quick DASH, job status, and patient satisfaction were reported and evaluated. Types of adverse events included mild or intermittent residual pain often triggered during exercise or cold, secondary subluxations, superficial infections, clinodactyly, two patients had stiff and painful fingers that led to fusion surgery, one patient had a completely stiff finger, and there were 2 swan neck deformations. One patient with diabetes mellitus, osteoarthritis resulted in a premature removal of the system at 18 days. It was reported that all fractures healed. Types and rates of adverse events compared favorably with types and rates reported in the literature for the predicate devices. Outcomes for pain, function, and patient satisfaction were also similar to those reported in the literature for the predicate devices and demonstrate the safety and efficacy of the Ligamentotaxor. The AREX Ligamentotaxor presents no new issues regarding safety and effectiveness as compared to legally marketed predicate devices.

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Ellen Hokanson Date
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arex USA LLC
% Ms. Ellen Hokanson
President
1335 Merrybrook Road
Collegeville, Pennsylvania 19403

AUG 17 2010

Re: K094043
Trade/Device Name: AREX Ligamentotaxor (LTX)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: August 13, 2010
Received: August 16, 2010

Dear Ms. Hokanson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K094043

Device Name: AREX USA Ligamentotaxor (LTX)

Indications for Use:

The Ligamentotaxor is an external fixation system intended for use in the treatment of complex fracture dislocations, stable and unstable dislocations, fracture luxations, and pilon fractures in the PIP joint.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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